### WAS Rec'd PCT/PIU 18 APR 2007

PTO-1390 (Rev. 07-2005) Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

INTERNATIONAL APPLICATION NO.

ATTORNEY'S DOCKET NUMBER

BHC 032003

U.S. APPILICATION NO. (If kpownsee 37 CFR 1.5)
PRIORITY DATE CLAIMED

PCT/EP2004/011101 5 October 2004 (05.10.2004) 18 October 2003 (18.10.2003)

TITLE OF INVENTION 5-Substituted -2-(Phenylmethyl)Thio-4-Phenyl-4H-1,2,4-Triazole Derivatives and Related Compounds as GABA-Agonists for the Treatment of Urinary Incontinence and Related.....

APPLICANT(S) FOR DO/EO/US

Bauser, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.

2. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.

3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.

INTERNATIONAL FILING DATE

|               | (5), (6), (9) and (21) indicated below.  |  |  |  |  |  |
|---------------|--|--|--|--|--|--|
| 4. 🗸          | The US has been elected (Article 31).  |  |  |  |  |  |
| 5.            | A copy of the International Application as filed (35 U.S.C. 371(c)(2))   |  |  |  |  |  |
|               | a. s attached hereto (required only if not communicated by the International Bureau).  |  |  |  |  |  |
|               | b. has been communicated by the International Bureau.  |  |  |  |  |  |
|               | c. is not required, as the application was filed in the United States Receiving Office (RO/US).  |  |  |  |  |  |
| 6.            | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).   |  |  |  |  |  |
|               | a. is attached hereto.   |  |  |  |  |  |
| _             | b. has been previously submitted under 35 U.S.C. 154(d)(4).  |  |  |  |  |  |
| <sub>7.</sub> | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))   |  |  |  |  |  |
|               | a. are attached hereto (required only if not communicated by the International Bureau).  |  |  |  |  |  |
|               | b. have been communicated by the International Bureau.   |  |  |  |  |  |
|               | c. have not been made; however, the time limit for making such amendments has NOT expired.   |  |  |  |  |  |
|               | d. Ave not been made and will not be made.   |  |  |  |  |  |
| 8.            | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).                                    |  |  |  |  |  |
| 9.            | An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).   |  |  |  |  |  |
| 10.           | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). |  |  |  |  |  |
| Item          | Items 11 to 20 below concern document(s) or information included:  |  |  |  |  |  |
| 11. 🗸         | An Information Disclosure Statement under 37 CFR 1.97 and 1.98.  |  |  |  |  |  |
| 12.           | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.                              |  |  |  |  |  |
| 13.           | A preliminary amendment.   |  |  |  |  |  |
| 14.           | An Application Data Sheet under 37 CFR 1.76.   |  |  |  |  |  |
| 15. 📖         | A substitute specification.  |  |  |  |  |  |
| 16.           | A power of attorney and/or change of address letter.   |  |  |  |  |  |
| 17.           | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.                                  |  |  |  |  |  |
| 18.           | A second copy of the published International Application under 35 U.S.C. 154(d)(4).  |  |  |  |  |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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| U.S. APPLICA  | ATION               | yQ⊷(if kapwn    | , see 37 CTR 1.5                     | ) INTERNATIONAL A            | PPLICATION NO.    |                | ATTORNEY'S DO       | CKET NUMBER  |  |  |
|---|---------------------|-----------------|--------------------------------------|------------------------------|-------------------|----------------|---------------------|--------------|--|--|
| U.S. APPLICATION NO. (if known, see 370k 1.5)   |                     |                 | 822                                  | PCT/EP200                    | PCT/EP2004/011101 |                |                     | BHC 032003   |  |  |
| 20. Other items or information: 1) Certificate of Mailing under 37 C.F.R. 1.10 2) Copy of the International Search Report (37 CFR 1.492(b)(3)) 3) Itemized Return Receipt Postcard  |                     |                 |                                      |                              |                   |                |                     |              |  |  |
| The fo  | llowing             | fees have h     | seen submitted                       |                              |                   | СА             | LCULATIONS          | PTO USE ONLY |  |  |
| The following fees have been submitted  21.  Basic national fee (37 CFR 1.492(a))   |                     |                 | \$300                                | \$                           | 300.00            | 1 TO GOL GIVE! |                     |              |  |  |
| 22. 🖊 Exa   |                     |                 |                                      |                              |                   |                |                     |              |  |  |
| If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 All other situations  |                     |                 |                                      |                              |                   | \$             | 200.00              |              |  |  |
| 23. Search fee (37 CFR 1.492(b))  If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0  Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority                           |                     |                 |                                      |                              |                   | \$             | 400.00              |              |  |  |
| TOTAL OF 21, 22 and 23 =  |                     |                 |                                      |                              |                   | \$900.00       |                     |              |  |  |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  Total Sheets Extra Sheets Number of each additional 50 or fraction RATE |                     |                 |                                      |                              |                   |                |                     |              |  |  |
|   | ļ                   |                 | thereof (round up to a whole number) |                              |                   |                |                     |              |  |  |
| <b>108</b> - 100 =  | 108 - 100 = 8 /50 = |                 | 1                                    | x \$250                      | \$                | 250            | <u>'</u>            |              |  |  |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).   |                     |                 |                                      |                              | \$                |                |                     |              |  |  |
| CLAIMS  |                     | NUMB            | ER FILED                             | NUMBER EXTRA                 | RATE              | \$             |                     |              |  |  |
| Total claims  | 3                   |                 | 18 - 20 =                            | 0                            | x \$ 50           | \$             | 0                   |              |  |  |
| Independent claims  |                     |                 | 6 - 3 =                              | 3                            | x <b>\$200</b>    | \$             | 600                 |              |  |  |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) 0 + \$360   |                     |                 |                                      |                              | + \$360           | \$             | 0                   |              |  |  |
| TOTAL OF ABOVE CALCULATIONS =  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  |                     |                 |                                      |                              |                   | \$             | 1750                |              |  |  |
| Applicant cl  | aims si             | mall entity sta | atus. See 37 CF                      | R 1.27. Fees above are reduc |                   |                |                     |              |  |  |
| SUBTOTAL =  |                     |                 |                                      |                              |                   | \$             | 1750                |              |  |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).   |                     |                 |                                      |                              | \$                |                |                     |              |  |  |
| TOTAL NATIONAL FEE =  |                     |                 |                                      |                              | \$ 1750           |                |                     |              |  |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +  |                     |                 |                                      |                              | \$                |                |                     |              |  |  |
| TOTAL FEES ENCLOSED =   |                     |                 |                                      |                              |                   |                | 1750                |              |  |  |
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|   |                     |                 |                                      |                              |                   | Amo            | ount to be          | \$           |  |  |

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| a. A check in the amount of \$ to co  | over the above fees is enclosed.  |  |  |  |  |  |
|---|---|--|--|--|--|--|
| b. Please charge my Deposit Account No13-3372 in the A duplicate copy of this sheet is enclosed.                                    | amount of \$to cover the above fees.  |  |  |  |  |  |
|   | The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 13-3372. A duplicate copy of this sheet is enclosed.  Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. |  |  |  |  |  |
|   |   |  |  |  |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has no and granted to restore the International Application to pending sta | ot been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed  |  |  |  |  |  |
|   |   |  |  |  |  |  |
| SEND ALL CORRESPONDENCE TO: Customer No. 3596   | 9 William F. Gray   |  |  |  |  |  |
| Jeffrey M. Greenman   | SIGNATURE   |  |  |  |  |  |
| Vice President  | William F. Grav   |  |  |  |  |  |
| Patents and Licensing   | NAME  |  |  |  |  |  |
| Bayer Pharmaceuticals Corporaton  | 31018   |  |  |  |  |  |
| 400 Morgan Lane   | REGISTRATION NUMBER   |  |  |  |  |  |
| West Haven, CT 06516  |   |  |  |  |  |  |
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Date of Deposit: 18 April 2006

Express Mail Label Number: EQ 409 313 917 US

#### **PATENT**

### IAP12 Rec'd PCT/PTO 18 APR 2006

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bauser, Marcus

Serial No.: [to be assigned] National Stage Filing of PCT/EP2004/011101

Filed: herewith

For: 5-Substituted -2-(Phenylmethyl)Thio-4-Phenyl-4H-1,2,4-Triazole Derivatives and Related Compounds as GABA-Agonists for the Treatment of Urinary Incontinence and Related Diseases

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#### **CERTIFICATE OF MAILING UNDER 37 CFR 1.10**

| I hereb   | y certify that the attached correspondence comprising:   |  |  |  |  |  |  |
|-----------|--|--|--|--|--|--|--|
| <b>∑</b>  | Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing under 35 U.S.C. 371 [IN DUPLICATE];   |  |  |  |  |  |  |
| <b>V</b>  | Application Data Sheet under 37 C.F.R. 1.76;   |  |  |  |  |  |  |
|           | Preliminary Amendment;   |  |  |  |  |  |  |
|           | Oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4));  |  |  |  |  |  |  |
|           | English Translation of the Application (35 U.S.C. 371(c)(2));  |  |  |  |  |  |  |
| <b>✓</b>  | Copy of the International Application as filed (35 U.S.C. 371(c)(2));  |  |  |  |  |  |  |
|           | Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98 consisting of:  1) Transmittal of Information Disclosure Statement under 37 C.F.R. 1.97(b)(2)  2) Form(s) PTO/SB/08A-B [substitute for form 1449/PTO] (37 C.F.R. 1.98(a)(b))  3) Copies of Cited References (37 C.F.R. 1.98(d)) |  |  |  |  |  |  |
|           | Other:   |  |  |  |  |  |  |
| <b></b> ✓ | Itemized Return Receipt Post Card.   |  |  |  |  |  |  |
|           | ne date shown below, being deposited with the United States Postal Service, in an envelope bress Mail Post Office to Addressee" Mailing Label NumberEQ 409 313 917 US sed to:  |  |  |  |  |  |  |
| 11        | Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450   |  |  |  |  |  |  |
|           | Date Signature of Person Certifying / William F. Gray  |  |  |  |  |  |  |